Exhibit B:

Complaint and Jury Demand

(Dated: January 7, 2020)

IN THE CIRCUIT COURT FOR BALTIMORE CITY

ANDREA L. AUCKER *
760 Walnut Street
Pottsville, Pennsylvania 17901 *

LEANNE M. BAKER *
DANNY L. BAKER
902 Evergreen St. *
Princeton, Texas 75407 *

MARY L. BODDIE *
412 Lincoln Dr. Case No. _____
Glen Burnie, Maryland 21060 *

REGINALD A. BRASHEARS, SR. *
SORAYA BRASHEARS
120 Point Pleasant Road *
Glen Burnie, Maryland 21060

CLAUDIA GARRETT *
161 Obery Court
Annapolis, Maryland 21401 *

GEORGE R. GRAHAM *
OLETA K. GRAHAM
3616 Marica Court *
Myrtle Beach, South Carolina 29579 *

JUDY A. HEBBARD *
6205 Mallard Lane
Lothian, Maryland 20711 *

DAWN M. KELLAR *
1421 Rowe Drive
Glen Burnie, Maryland 21061 *

TAMMIE E. LANE *
120 Cee Jay Rd.
Chestertown, Maryland 21620 *

DIANE MARUT *
307 Chesapeake Ave.
Baltimore, Maryland 21225 *

DEBORAH A. MCCULLY *
WAYNE MCCULLY
984 Day Star Way *
Loris, South Carolina 29569

*

CATHY J. PAQUET
RICHARD PAQUET *
3313 Carlisle Drive
Knoxville, Maryland 21758 *

NATASHA F. QUEEN *
7834 Woodside Terrace, Apt. 102
Glen Burnie, Maryland 21061 *

TERESA M. STANCLIFF *
KEITH A. STANCLIFF
5026 Iroquois Street *
College Park, Maryland 20740

Plaintiffs, *

*

v.

UNIVERSITY OF MARYLAND MEDICAL *
SYSTEM
22 South Greene Street *
Baltimore, Maryland 21201

*

Serve On: *
Megan M. Arthur, Resident Agent
250 W. Pratt Street, 24th Floor *
Baltimore, Maryland 21201

*

and

BALTIMORE WASHINGTON MEDICAL *
CENTER, INC.
301 Hospital Drive *
Glen Burnie, Maryland 21061

*

Serve On: *
Megan M. Arthur, Resident Agent
250 W. Pratt Street, 24th Floor *
Baltimore, Maryland 21201

*

and

RANDY DAVIS, M.D.
1 Purdy Point Road
Gibson Island, Maryland 21056

and

RFD MANAGEMENT, L.L.C.
1 Purdy Point Road
Gibson Island, Maryland 21056

Defendants.

* * * * * * * * * * * * * *

COMPLAINT

Plaintiffs, by and through their undersigned attorneys, Sullivan Papain Block McGrath & Cannavo P.C., allege at all relevant times hereinafter mentioned, as follows:

INTRODUCTION

1. From 2005 through 2012, Dr. Randy Davis, a prominent orthopedic spine surgeon at the University of Maryland Baltimore Washington Medical Center ("UM-BWMC")[1], implanted "adulterated" and "misbranded"[2] and likely counterfeit spinal fusion instrumentation in his patients in violation of State and Federal laws. As a result, many of Dr. Davis's spinal fusion patients have suffered the severe effects of having non-FDA approved and potentially phony pedicle screws, screw caps, rods, and cages implanted in their spines. The massive institutional corruption at the University of Maryland Medical System that spanned seven years enabled Dr. Davis to receive hundreds of thousands of dollars and other lavish illegal kickbacks from Spinal Solutions, LLC, in exchange for UMMS's illegal purchase of millions of dollars of Spinal Solutions' non-FDA approved "adulterated" and "misbranded" instrumentation. This fraudulent instrumentation – sold

[1] UM-BWMC is owned and operated by the University of Maryland Medical System ("UMMS"), and therefore known as one of the UMMS member hospitals.
[2] MD. CODE ANN., HEALTH-GEN. § 21-217 (2016); 21 U.S.C. § 352 (2012).

to UMMS by Spinal Solutions, a little-known west coast distributor turned counterfeit manufacturer – somehow eluded all UMMS safety and supply chain checks before implantation by Dr. Davis in approximately 250 unwitting UM-BWMC patients. When the substandard spinal components failed, causing severe and life-threatening injuries to their patients, Dr. Davis removed and disposed of the hardware without sending it to pathology or giving it back to his patients, and UMMS/UM-BWMC ignored their duties to report the adverse outcomes to the Food and Drug Administration under 21 C.F.R. § 803. Instead, UMMS continued purchasing the misbranded and adulterated hardware, and Dr. Davis continued implanting it in his patients' backs.

After this illicit scheme involving Dr. Davis, UM-BWMC/UMMS, and Spinal Solutions came to light in a California Complaint for health care fraud filed in February 2015, UM-BWMC/UMMS responded swiftly by sending fraudulent "hush" letters to Dr. Davis's patients for the clear purpose of concealing their unconscionable conduct and escaping liability. The letters provided specious assurances that non-FDA Spinal Solutions hardware was never received by UM-BWMC or used in spinal surgeries at UM-BWMC, when UM-BWMC had actual knowledge that the contrary was true. At every turn, Dr. Davis and UM-BWMC/UMMS put their pecuniary interests ahead of the welfare of their patients, including the Plaintiffs named herein, and caused immeasurable physical and emotional damage to hundreds of lives.

PARTIES

2. Andrea Aucker is an adult individual residing at 760 Walnut Street, Pottsville, PA. At all times relevant hereto, Ms. Aucker received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

3. Le Anne Baker is an adult individual residing at 902 Evergreen Street, Princeton, Texas. At all times relevant hereto, Mrs. Baker was a resident of the State of Maryland and received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

4. Danny Baker is an adult individual residing at 902 Evergreen Street, Princeton, Texas, and is the husband of Plaintiff Le Anne Baker. At all times relevant hereto, Mr. Baker was a resident of the State of Maryland.

5. Marry Boddie is an adult individual residing at 412 Lincoln Drive, Glen Burnie, Maryland. At all times relevant hereto, Ms. Boddie was a resident of the State of Maryland and received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

6. Reginald Brashears, Sr. is an adult individual residing 120 Point Pleasant Road, Glen Burnie, Maryland. At all times relevant hereto, Mr. Brashears was a resident of the State of Maryland and received medical treatment for his back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and he underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

7. Soraya Brashears is an adult individual residing at 120 Point Pleasant Road, Glen Burnie, Maryland, and is the wife of Plaintiff Reginald Brashears, Sr. At all times relevant hereto, Mrs. Brashears was a resident of the State of Maryland.

8. Claudia Garrett is an adult individual residing 161 Obery Court, Annapolis, Maryland. At all times relevant hereto, Ms. Garrett was a resident of the State of Maryland and

received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

9. George Graham is an adult individual residing at 3616 Marica Court, Myrtle Beach, South Carolina. At all times relevant hereto, Mr. Graham was a resident of the State of Maryland and received medical treatment for his back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and he underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

10. Oletta Graham is an adult individual residing at 3616 Marica Court, Myrtle Beach, South Carolina, and is the wife of Plaintiff George Graham. At all times relevant hereto, Mrs. Graham was a resident of the State of Maryland.

11. Judy Hebbard is an adult individual residing 6205 Mallard Lane, Lothian, Maryland. At all times relevant hereto, Ms. Hebbard was a resident of the State of Maryland and received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

12. Dawn Kellar is an adult individual residing at 1421 Rowe Drive, Glen Burnie, Maryland. At all times relevant hereto, Ms. Kellar was a resident of the State of Maryland and received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

13. Tammie Lane is an adult individual residing 120 Cee Jay Road, Chestertown, Maryland. At all times relevant hereto, Ms. Lane was a resident of the State of Maryland and

received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

14. Diane Marut is an adult individual residing at 307 Chesapeake Avenue, Baltimore, Maryland. At all times relevant hereto, Ms. Marut was a resident of the State of Maryland and received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

15. Deborah McCully is an adult individual residing at 984 Day Star Way, Loris, South Carolina. At all times relevant hereto, Mrs. McCully was a resident of the State of Maryland and received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

16. Wayne McCully is an adult individual residing at 984 Day Star Way, Loris, South Carolina, and is the husband of Plaintiff Deborah McCully. At all times relevant hereto, Mr. McCully was a resident of the State of Maryland.

17. Cathy Paquet is an adult individual residing at 3313 Carlisle Drive, Knoxville, Maryland. At all times relevant hereto, Mrs. Paquet was a resident of the State of Maryland and received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

18. Richard Paquet is an adult individual residing at 3313 Carlisle Drive, Knoxville, Maryland, and is the husband of Plaintiff Cathy Paquet. At all times relevant hereto, Mr. Paquet was a resident of the State of Maryland.

19. Natasha Queen is an adult individual residing at 7834 Woodside Terrace, Apt. 102, Glen Burnie, Maryland. At all times relevant hereto, Mrs. Queen was a resident of the State of Maryland and received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

20. Teresa Stancliff is an adult individual residing at 5026 Iroquois Street, College Park, Maryland. At all times relevant hereto, Mrs. Stancliff was a resident of the State of Maryland and received medical treatment for her back injuries from Defendant Dr. Randy Davis in Glen Burnie, Maryland, and she underwent spinal fusion using Spinal Solutions non-FDA approved substandard hardware at UM-BWMC in Glen Burnie, Maryland.

21. Keith Stancliff is an adult individual residing at 5026 Iroquois Street, College Park, Maryland, and is the husband of Teresa Stancliff. At all times relevant hereto, Mr. Stancliff was a resident of the State of Maryland

22. At all times herein relevant, Defendant Randy Davis, M.D., was a duly licensed physician holding himself out to the general public as a competent and skillful physician with special training in the field of orthopedic spinal surgery and as an individual who would properly monitor, attend to, examine, diagnose, treat and refer patients who might submit to his care. As such, Dr. Davis owed to Plaintiffs a duty to render that degree of care and treatment which is ordinarily rendered by those who devote special study and attention to the practice of orthopedic spinal surgery, including the full disclosure of all material risks associated with the care and

treatment of Plaintiffs. Upon information and belief, Dr. Davis is a resident of Anne Arundel County, Maryland, who at all relevant times carried out the practice of medicine in Anne Arundel County, Maryland.

23. At all times herein relevant, Defendant UM-BWMC was and is a corporation organized under the laws of the State of Maryland, with its principal place of business at 301 Hospital Drive, Glen Burnie, Maryland. UM-BWMC was at all times herein relevant, a medical facility offering medical and other related services to the general public. As such, UM-BWMC, its agents, servants and/or employees, medical staff and consultants held themselves out as practicing ordinary standards of medical, hospital and nursing care and, as such, owed a duty to the Plaintiffs to render and provide health care within the ordinary standards of medical, hospital and nursing care, including the full disclosure of all material risks associated with the care and treatment of the Plaintiffs. At all relevant times hereto, Dr. Davis was employed by, or was the actual and/or apparent agent of, or otherwise practiced medicine, on behalf of UM-BWMC.

24. At all times herein relevant, Defendant UMMS was and is a corporation organized under the laws of the State of Maryland, with its principal place of business at 22 South Greene Street, Baltimore, Maryland. UMMS was at all times herein relevant, a medical facility offering medical and other related services to the general public. As such, UMMS, its agents, servants and/or employees, medical staff and consultants held themselves out as practicing ordinary standards of medical, hospital and nursing care and, as such, owed a duty to the Plaintiffs to render and provide health care within the ordinary standards of medical, hospital and nursing care, including the full disclosure of all material risks associated with the care and treatment of the Plaintiffs. At all times herein relevant, Dr. Davis was employed by, or was the actual and/or apparent agent of, or otherwise practiced medicine, on behalf of UMMS.

25. On information and belief, Defendants UM-BWMC and UMMS were the actual and/or apparent agents, representatives, joint venturers, alter egos, co-conspirators, consultants, predecessors, successors, servants or employees of each other.

26. In doing the acts alleged herein, Defendants BWMC and UMMS were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence and ratification of each other.

27. At all relevant times, RFD Management, LLC, ("RFD Management") was a corporation organized under the laws of the state of Maryland with its principal place of business at 1 Purdy Point, Gibson Island, Maryland 21056. On information and belief, RFD Management was a physician owned distributorship formed for the sole purpose of generating income for Dr. Davis from the sale of medical devices that he used in surgeries on his patients at UM-BWMC, including the Plaintiffs.

28. At all relevant times, Dr. Davis was the actual and/or apparent agent, servant, or employee of UM-BWMC, UMMS, and RFD Management and was acting in the course and scope of his duties as such (Dr. Davis, UM-BWMC, UMMS, and RFD Management are hereinafter collectively referred to as the "Health Care Providers" and/or "Defendants").

29. On information and belief, at all relevant times, the Health Care Providers committed tortious acts within the State of Maryland causing injury within the State of Maryland out of which acts these causes of action arise.

JURISDICTION & VENUE

30. The Circuit Court for Baltimore City has jurisdiction over the subject matter of this action pursuant to, *inter alia*, Md. Code Ann., Cts. & Jud. Proc. Art. §1-501. This Court has

personal jurisdiction over the Defendants pursuant to, *inter alia*, Md. Code Ann., Cts. & Jud. Proc. Art. §§6-102 and 6-103.

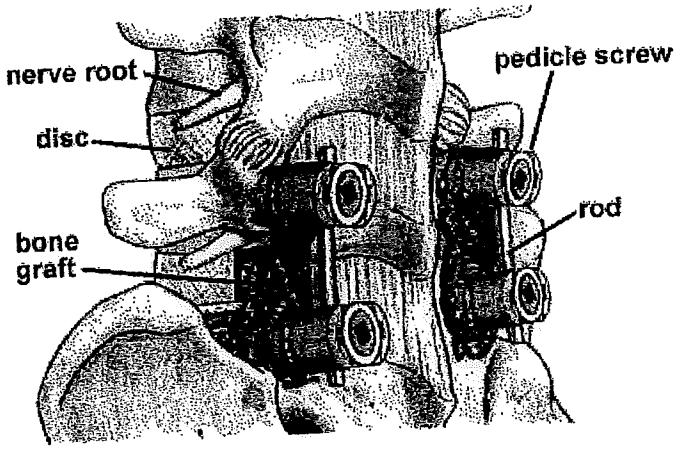
31. The amount of the claims contained herein exceed $30,000 and therefore jurisdiction lies exclusively in the Circuit Court.

32. Venue in this action is proper in Baltimore City, Maryland based on the Health Care Providers' places of business pursuant to, *inter alia*, Md. Code Ann., Cts. & Jud. Proc. Art. §§ 6-201, 6-202.

FACTS COMMON TO ALL COUNTS

A. Background on Instrumented Spinal Fusion Surgery

33. Instrumented spinal fusion is a complex and invasive surgery to join or fuse two or more vertebrae. The intent of the procedure is to use implantable metal fixation devices (screws, rods, cages, etc.) to immobilize the spine and prevent movement between the vertebrae while bone graft material implanted during the surgery is able to cause growth of new bone, providing permanent stabilization to the patient's spine.



34. Until, and if, this permanent fusion occurs, the implantable metal fixation devices are the sole source of stability in the patient's spine and any failure in these devices will prevent successful fusion and can cause permanent and life-threatening injuries.

35. It is therefore critical that the fixation devices used in instrumented spinal fusion surgeries be free from any defect, design or otherwise, which may increase the risk that the hardware will break, bend, loosen, or be otherwise compromised before the fusion occurs.

36. To help minimize the occurrence of failed surgeries due to inferior medical devices, the Department of Health and Human Services, through the Food and Drug Administration ("FDA"), has promulgated a comprehensive regulatory scheme governing the design, manufacturing, marketing, and handling of medical devices. *See* 21 C.F.R. §800 *et. seq.*

B. Spinal Solutions' Relationship with Dr. Davis, UM-BWMC, and UMMS

37. On information and belief, prior to 2005, Spinal Solutions acted solely as a medical device distributor, accepting inventory of medical devices on consignment from various manufacturers and then marketing and distributing those devices to a network of health care providers.

38. Serving in this limited "pass-through" function within the medical device market, Spinal Solutions was subject to relatively few of the aforementioned FDA regulations governing medical devices.

39. In or around 2005, however, Spinal Solutions retained a local California machinist specializing in airplane parts to manufacture counterfeit copies of certain implantable spinal fixation devices.

40. On information and belief, Spinal Solutions mixed these counterfeit medical devices with other medical devices and sold the "mixed bag" as Spinal Solutions branded medical devices.

41. In addition to the counterfeiting, the mere act of repackaging medical devices manufactured by a third party and marketing them under the Spinal Solutions brand rendered

Spinal Solutions a manufacturer of the medical devices under the FDA regulatory definition and therefore subject to dozens of additional regulations.

42. Neither Spinal Solutions nor the machinist, William Crowder, had any experience manufacturing medical devices and had never applied for, much less obtained, FDA approval to do so. This failure was readily discoverable by the UMMS, UM-BWMC, and Dr. Davis through the FDA's publicly available database of medical device approvals.

43. Equally discoverable to UMMS, UM-BWMC and Dr. Davis was the fact that none of the Spinal Solutions hardware was properly marked with serial, lot, batch, and catalog numbers, as required by federal and state law. On August 16, 2011, Roger Williams, the owner of Spinal Solutions, issued a sworn affidavit in which he attested that: "[t]he distribution of products from Spinal Solutions, LLC, are not documented and no shipping records are maintained" and that "[s]uch information as product lot numbers, quantity, and destination have not been recorded." Moreover, the Spinal Solutions hardware was not accompanied by label or "sticker" with the serial, lot, batch and catalog numbers, as reputable implantable devices are.

44. Instead of heeding these glaring warning signs, UMMS and UM-BWMC operating room personnel either left this critical identifying information blank on their patients' Intraoperative Records, or worse yet, recorded fictitious information in their medical records. By way of example, compare the implant logs for the **"Spinal Solutions" 6.0 x 45 mm screws** used in the surgeries on Plaintiff Boddie, Plaintiff Baker, and Plaintiff Hebbard:

• **Plaintiff Boddie:**	**Serial no.: n/a**	**Lot no.: 600045**	**Catalog no.: n/a**
• **Plaintiff Baker:**	**Serial no.: 60006-45**	**Lot no.: n/a**	**Catalog no.: n/a**
• **Plaintiff Hebbard:**	**Serial no.: n/a**	**Lot no.: n/a**	**Catalog no.: 60006-45**

While most of the critical identifying information is missing, the number recorded is a variation on the size of the screw used. More egregiously, the identical number is recorded as the serial number, lot number, and catalog number in three different surgeries.

45. In late 2011, a site visit by FDA inspectors revealed that not only was Spinal Solutions "manufacturing" medical devices without approval by virtue of repackaging them, but it was also doing so in violation of dozens of federal regulations designed to prevent patient injuries caused by defectively manufactured, marketed, and distributed medical devices.

46. Prior to unraveling, Spinal Solutions was only able to effectuate this fraudulent scheme by recruiting a handful of surgeons around the country, including Dr. Davis, who were willing and able to influence their employers, including UMMS and UM-BWMC, to purchase Spinal Solutions branded medical devices at the risk of causing catastrophic injuries to their patients.

47. With no reputation in the industry, no track-record as a manufacturer or distributor of self-branded medical devices, and no FDA approvals to manufacture and/or sell such devices, Spinal Solutions resorted to "convincing" surgeons by doling out sham consulting contracts and lavishing them with kickbacks in the form of cash, valuable coins, sports memorabilia, air travel, entertainment, and use of multiple private jets owned and/or leased by Spinal Solutions' founder, Roger Williams.

48. On information and belief, sometime after Spinal Solutions began illegally selling self-branded, counterfeit medical devices, Dr. Davis entered into one such sham consulting agreement worth hundreds of thousands of dollars, and subsequently used his influence within UMMS/UM-BWMC to cause UMMS/UM-BWMC to contract with Spinal Solutions to provide the spinal fusion instrumentation that Dr. Davis implanted into hundreds of patients, including the Plaintiffs.

49. In May 2005, in or around the time in which Dr. Davis entered into the sham consulting agreement with Spinal Solutions, Dr. Davis created RFD Management, L.L.C., a

physician owned distributorship ("POD"), which he operated for the stated purpose to "(a) buy, sell, and lease medical equipment and supplies . . ." Upon information and belief, illegal remuneration was paid to Dr. Davis by Spinal Solutions through his POD.[3] RFD Management was terminated in 2012 in or around the same time Spinal Solutions shuttered its operations.

50. At all relevant times, UMMS/UM-BWMC had absolute authority over the purchase of medical devices for use in procedures performed by Dr. Davis at UM-BWMC and UMMS/UM-BWMC was invoiced directly for each such procedure, including those performed on Plaintiffs.

51. At all relevant times, UMMS/UM-BWMC also had authority over the billing of medical devices for use in procedures performed by Dr. Davis at UM-BWMC and UMMS/UM-BWMC. When UMMS/UM-BWMC billed its patients for Spinal Solutions instrumentation, it arbitrarily billed them different amounts for the identical products even though the cost to UMMS/UM-BWMC was the same in each case. For example, on April 20, 2010, Plaintiff Mary Boddie was billed for $1300 for each 6.0 x 45 mm Spinal Solutions screw, while Plaintiff Le Anne Baker was only billed $1048.95 for the same screws on November 16, 2010, and Plaintiff Dawn Kellar was billed $2,815.15 for each of the same screws on March 18, 2011.

52. Despite the open and obvious conflict of interest, UMMS/UM-BWMC, part of a sophisticated, multi-billion dollar healthcare system, allowed Dr. Davis to influence the purchase of millions of dollars of critically consequential medical devices from a previously unknown medical device wholesaler on the other side of the country.

[3] POD's were the subject of a 2011 U.S. Senate Finance Committee Investigation, which was then updated in 2016. The Senate Finance Committee's Investigation concluded that there is "little doubt" that "POD financial incentives can and do alter surgeon behavior and result in higher utilization rate by POD surgeons." In other words, surgeons with PODs continue to use the products they are selling whether they work or not. The Senate Finance Committee also cited as a "troubling report," "surgeons performing revision surgery to replace previously implanted hardware with the same or nearly equivalent hardware sold by their own PODs." Finally, the Senate Finance Committee concluded that the "steady flow of income" produced by a POD, "present[s] an inherent conflict of interest that can put the physician's medical judgment at odds with the patient's best interests."

53. On information and belief, no other surgeon within UMMS' vast network of physicians had ever worked with Spinal Solutions medical devices, yet UMMS/UM-BWMC either failed to perform even the most basic level of due diligence before entering into a contract or intentionally disregarded the obvious warning signs. Even the most basic inquiry would have revealed that Spinal Solutions' sale of self-branded medical devices was prohibited by numerous state and federal laws and posed a grave threat to their patients. Likewise, such an inquiry would have revealed that Spinal Solutions held no 510K clearances or PMAs from the FDA.

54. In the alternative, UMMS/UM-BWMC consciously and deliberately conspired with Dr. Davis to use non-approved, substandard, and/or counterfeit medical devices in hundreds of patients between 2005 and 2012, including the Plaintiffs.

55. Nevertheless, at all times relevant herein, UM-BWMC and UMMS had absolute authority and discretion over the retention of medical device vendors, including Spinal Solutions, and/or the purchase of surgical supplies, including the Spinal Solutions implantable spinal fixation devices used in Plaintiffs' surgeries.

56. UM-BWMC, is a "member facility" under the UMMS corporate umbrella. On information and belief, UMMS maintains comprehensive and controlling vendor management and procurement policies and procedures that apply to all UMMS facilities, including UM-BWMC.

57. Therefore, on information and belief, a UMMS employee and/or agent either had direct signatory authority over the purchase of the Spinal Solutions devices used in Plaintiffs' instrumented spinal fusion surgery and/or directly entrusted that authority to an employee/agent of UM-BWMC.

58. UMMS/UM-BWMC purchased and received millions of dollars in non-FDA approved, misbranded and/or adulterated, substandard, and/or counterfeit medical devices directly from Spinal Solutions and/or through RFD Management.

59. At all times relevant hereto, the readily apparent dangers of using substandard, non-conforming implantable fixation devices include, but are not limited to:

a. Deep surgical site infection caused by the mishandling of implantable medical devices. It is well understood that only a few bacteria introduced on the surface of an implantable medical device like the ones used in Plaintiff's surgeries, are capable of causing severe deep tissue infections; and

b. Mechanical device failure in any one of the many component devices used during an instrumented spinal fusion surgery, including fracture, pull-out, etc.

60. Each of these outcomes results in foreseeably catastrophic complications including permanent physical disability, chronic pain, multiple additional operations, paralysis and/or death, among others.

61. Even after patients suffered such complications and resultant injuries following surgery by Dr. Davis with Spinal Solutions devices, Dr. Davis, UM-BWMC, and UMMS unconscionably continued purchasing and implanting the non-approved, substandard, and/or counterfeit devices.

62. After Spinal Solutions' illicit scheme and UM-BWMC's and Dr. Davis's involvement therein was exposed, UMMS and UM-BWMC acted swiftly to deploy a "cover up" by sending "hush" letters to Dr. Davis's patients, including the Plaintiffs. These letters, sent under the signature of Karen Olscamp, then President and COO of UM-BWMC, stated: "*We want to assure you that we have found no evidence to date that any of the alleged non-FDA approved hardware was ever delivered to or used in spinal surgeries at UM BWMC.* . . . we wanted to let you know we have reviewed your medical record carefully, and to assure you there is no reason

for concern and no evidence that you received any of the alleged non-FDA approved hardware." (Emphasis in original) (Letter attached hereto as Exhibit 1). To the contrary, these are fraudulent representations in that *all* spinal solutions hardware received and used by Defendants was non-FDA approved, and the medical records do not contain the required tracking information, *i.e.*, serial, lot and batch numbers, for any of the Spinal Solutions instrumentation implanted into Plaintiffs' spines, which means that the Plaintiffs' medical records did not contain the information necessary for UMMS's assurances to be based upon. Accordingly, at the time UMMS and UM-BWMC made these assurances, they had actual knowledge of their falsity. Moreover, more than two years before Ms. Olscamp's letter was sent to Plaintiffs, the FDA sent a "Warning Letter" to Spinal Solutions, which identified Spinal Solutions products as "adulterated" and failing to conform to "current good manufacturing practice requirements." This letter was publicly available at the time Ms. Olscamp's letter was sent to Plaintiffs, and can be found on the FDA's website and by a simple Google search.

63. The clear intent of Defendants' letter was to further conceal their abhorrent conduct and avoid any potential liability.

C. The Failure to Report Adverse Events

64. FDA regulations require medical device user facilities, including UMMS/UM-BWMC, to create reports following each incident in which there is reason to suggest that a serious patient injury, including the need for surgical intervention to prevent permanent injury, can be attributed to the failure of a medical device, whether because of a defect or user error. *See* 21 C.F.R. §803 *et. seq.*

65. On information and belief, in addition to failing to report each such incident related to Spinal Solutions devices back to Spinal Solutions, Dr. Davis and UMMS/BWMC consciously

and deliberately failed to submit annual summary reports of these incidents to the FDA as required by law. *See* 21 C.F.R. §§ 803.10; 803.33.

66. This intentional and fraudulent concealment of serious injuries likely caused and/or contributed to by the inferior quality of the Spinal Solutions devices subverted the clear purpose of the FDA reporting rules. Specifically, it prevented either the FDA or the public from discovering that Spinal Solutions was marketing the illegally manufactured medical devices.

67. Such a discovery would have alerted state and federal regulatory authorities, insurance providers, other health care providers, and patients that the Spinal Solutions medical devices Dr. Davis had used and/or was planning to use were non-approved, substandard, and/or counterfeit.

68. Instead, for a period of at least seven years, Dr. Davis and UMMS/UM-BWMC routinely purchased non-FDA approved, substandard, misbranded, adulterated, and/or counterfeit spinal fixation devices from Spinal Solutions and implanted those devices into their patients, including, Plaintiffs.

D. Plaintiffs Surgeries and Resulting Injuries

Plaintiff Andrea Aucker

69. By February 2009, Plaintiff Andrea Aucker had a long history of back pain and Defendant Dr. Davis prescribed an L1-L2 discectomy and an L1-L2 interbody fusion. As indicated by the Operative Report, and the Intraoperative record which noted the presence of Spinal Solutions' sales representative Ron O'neal during the surgery, Dr. Davis planned on using Spinal Solutions instrumentation to perform the fusion, but abandoned the plan due to complications encountered.

70. Approximately two years later, on March 31, 2011, Andrea Aucker, at the age of 45, underwent an L3-L4 instrumented lumbar fusion surgery with Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

71. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of two 5.0 x 45 mm pedicle screws, two pedicle screw caps, one fixation rod, and one APLIF spacer. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

72. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Ms. Aucker's body as "Spinal Solutions vertebral screws."

73. It is clear that during Ms. Aucker's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

74. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

75. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers.

76. Ms. Aucker was billed for the substandard hardware used to perform her lumbar fusion surgery on March 31, 2011, and Ms. Aucker incurred out of pocket expenses related to the procedure.

77. Though Spinal Solutions hardware should never have been implanted in Ms. Aucker, and she should not have been billed for the substandard hardware, upon information and belief she was actually billed more for the Spinal Solutions pedicle screws than many other patients who received them. To this end, Ms. Aucker was billed $2,815 for each screw. Curiously, Plaintiff Tammie Lane and Plaintiff Claudia Garrett also had Spinal Solutions 5.0 x 45 mm screws implanted in their bodies, but neither were billed for their screws by UM-BWMC.

78. The APLIF device implanted in Ms. Aucker was the subject of a recall in 2013 due to "inadequate testing and documentation to demonstrate that it meets performance or safety standards." The recall further stated that "[t]hese inadequacies might result in product performance failures that could cause patient harm due to implant breakage, movement, or inadequate sterilization."

79. Despite this recall notice being issued and publicly available on the FDA's website, neither Dr. Davis, UM-BWMC, nor UMMS informed Ms. Aucker of the recall. Instead, UM-BWMC sent a letter to its patients, including Ms. Aucker, on July 13, 2015, falsely reassuring them that that no "... *non-FDA approved hardware was ever delivered to or used in spinal surgeries at UM BWMC.*" (Emphasis in original).

80. Ms. Aucker experienced no relief from the March 30, 2011 fusion and experienced a series of new painful conditions thereafter, including compression fractures, the need for another instrumented fusion surgery, and screw loosening.

81. As referenced in the preceding paragraph, in February 2014, Ms. Aucker was forced to undergo another instrumented fusion performed by Dr. Davis at BWMC, this time using Pinnacle and Titamed instrumentation. Interestingly, the manufacturer of the "Pinnacle" hardware is identified by UM-BWMC personnel in the Implant Log as "Pinnacle Spine Distribution," which upon information and belief, was not a manufacturer of spinal fusion implants at that time.

82. Ms. Aucker incurred medical expenses, which she would not have incurred had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

83. As a result of Spinal Solutions hardware being implanted in her spine, Ms. Aucker suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish.

Plaintiff Le Anne Baker

84. On November 16, 2010, Plaintiff Le Anne Baker, underwent a three-level lumbar fusion surgery at the L3-L4, L4-L5, and L5-S1 levels with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

85. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of eight 6.0 x 45 mm pedicle screws, eight pedicle screw caps, and two fixation rods. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

86. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Mrs. Baker's body as "Spinal Solutions pedicle screw instrumentation."

87. It is clear that during Mrs. Baker's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was

treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

88. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

89. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains product implant stickers and bar codes for other products implanted during the surgery, but no such stickers or bar codes for the Spinal Solutions instrumentation.

90. Mrs. Baker was billed for the substandard hardware used to perform her lumbar fusion surgery on November 16, 2010, and Mrs. Baker incurred out of pocket expenses related to the procedure.

91. Mrs. Baker experienced no relief from the procedure and instead experienced numbness and pain on the right side of her body from her hip to her knee, which did not dissipate.

92. On September 25, 2012, due to Mrs. Baker's continued pain caused by the substandard and non-FDA approved hardware, Dr. Davis performed explant surgery in which he removed all of the Spinal Solutions hardware previously implanted. During the surgery, "evidence of attenuation" was identified at the L4-L5 and L5-S1 levels.

93. The condition of the hardware cannot be evaluated now because Dr. Davis improperly discarded the explanted hardware without sending it to pathology or offering it to his patient. In addition, in violation of 21 C.F.R. § 803, et seq., no adverse event report was filed by Dr. Davis or UMMS/UM-BWMC.

94. Mrs. Baker incurred medical expenses, including for the explant surgery, which she would not have incurred had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

95. As a result of Spinal Solutions hardware being implanted in her spine, Mrs. Baker suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish. She still to this day has little feeling in her right foot and must walk with the assistance of a cane or walker.

Plaintiff Mary Boddie

96. On April 20, 2010, Plaintiff Mary Boddie, underwent a two-level lumbar fusion surgery at the L4-L5 and L5-S1 levels with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

97. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of two 6.0 x 5.0 mm pedicle screws, two 6.0 x 45 mm pedicle screws, two 6.0 x 40 mm pedicle screws, six pedicle screw caps, and two fixation rods. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

98. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Ms. Boddie's body as "Spinal Solutions pedicle screw instrumentation."

99. It is clear that during Ms. Boddie's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

100. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

101. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains a product implant sticker for another product implanted during the surgery, but no such stickers or bar codes for the Spinal Solutions instrumentation.

102. Ms. Boddie was billed for the substandard hardware used to perform her lumbar fusion surgery on April 20, 2010, and Ms. Boddie incurred out of pocket expenses related to the procedure.

103. Moreover, UMMS/UM-BWMC committed billing fraud by billing Ms. Boddie for two 4.0 mm x 12 mm Synthes Cannulated trauma screws that were not used. Interestingly, these FDA-approved screws that were not used were billed at $210.25 per screw, while the non-FDA approved Spinal Solutions screws were billed to Ms. Boddie at $1,300.00 per screw.

104. Just seven days after the aforementioned fusion surgery, Ms. Boddie was in tremendous pain and was diagnosed with a post-operative epidural hematoma. On April 27, 2010, Dr. Davis operated again to explore her lumbar wound and to drain the hematoma found in the area of the newly implanted Spinal Solutions instrumentation.

105. On June 9, 2010, after experiencing debilitating pain since the instrumented fusion, Dr. Davis performed revision surgery on Ms. Boddie at UM-BWMC. Ms. Boddie's pain was caused by "sequential loosening" and "dislodgment of the lower edge of the S1 screw" which was reportedly complicated by her body's inflammatory response to the substandard hardware. During this procedure, Dr. Davis removed a rod and three screw caps, discarded them without sending them to pathology or offering them to the patient, and replaced them with more Spinal Solutions hardware.

106. Ms. Boddie incurred medical expenses, including for two additional surgeries, which she otherwise would not have incurred, had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

107. As a result of Spinal Solutions hardware being implanted in her spine, removed, and re-inserted, Mrs. Boddie suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish. She still to this day walks with the assistance of a cane.

Plaintiff Reginald Brashears

108. After a history of back problems, Plaintiff Reginald Brashears sought help from Dr. Davis. Within months of becoming Dr. Davis's patient, on April 13, 2010, Mr. Brashears underwent a two-level lumbar fusion surgery at the L4-L5 and L5-S1 levels with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

109. In performing the surgery, upon information and belief, Dr. Davis implanted four 6.0 x 50 mm screws, four screw caps, and two fixation rods. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

110. It is clear that during Mr. Brashear's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

111. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

112. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers.

113. Mr. Brashears was billed for the substandard hardware used to perform his lumbar fusion surgery on April 13, 2010, and Mr. Brashears incurred out of pocket expenses related to the procedure.

114. Mr. Brashears experienced no relief from the procedure and instead experienced additional pain. After the surgery in April 2010, Mr. Brashears sought Dr. Davis's counsel due to the increased pain he was experiencing. Dr. Davis responded by telling Mr. Brashears that he must

seek assistance from a pain management physician, and Dr. Davis refused to continue to see Mr. Brashears because as Dr. Davis put it, he was "not doing workmen's comp cases anymore."

115. Mr. Brashears incurred medical expenses which he would not have incurred had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to him prior to being implanted.

116. As a result of Spinal Solutions hardware being implanted in his spine, Mr. Brashears lives in fear that his substandard non-FDA approved hardware will fail, and suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish.

Plaintiff Claudia Garrett

117. Plaintiff Claudia Garrett suffered from chronic back pain for a number of years. In or around 2010, she became a patient of Dr. Davis's. Within a short period of time of becoming Dr. Davis's patient, on February 23, 2011, Ms. Garrett underwent a lumbar fusion surgery at the L3-L4 level with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

118. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of two 5.0 x 45 mm pedicle screws, two pedicle screw caps, and one fixation rod, and an APLIF spacer. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

119. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Ms. Garrett's body as "Spinal Solutions fixation" and "Spinal Solutions screws."

120. It is clear that during Ms. Garrett's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was

treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

121. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

122. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains a product implant sticker for another product implanted during the surgery, but no such stickers or bar codes for the Spinal Solutions instrumentation.

123. Ms. Garrett was billed for the substandard hardware used to perform her lumbar fusion surgery on February 23, 2011, and Ms. Garrett incurred out of pocket expenses related to the procedure.

124. The APLIF device implanted in Ms. Garrett was the subject of a recall in 2013 due to "inadequate testing and documentation to demonstrate that it meets performance or safety standards." The recall further stated that "[t]hese inadequacies might result in product performance failures that could cause patient harm due to implant breakage, movement, or inadequate sterilization."

125. Despite this recall notice being issued and publicly available on the FDA's website, neither Dr. Davis, UM-BWMC, nor UMMS informed Ms. Garrett of the recall. Instead, UM-

BWMC sent a letter to its patients, including Ms. Garrett, on July 13, 2015, falsely reassuring them that that no "... *non-FDA approved hardware was ever delivered to or used in spinal surgeries at UM BWMC.*" (Emphasis in original).

126. Ms. Garrett experienced no relief from the procedure and instead experienced continued and worsening pain. In or around April 4, 2011, she received a steroid injection, which also did not give her adequate relief.

127. As a result of the failed Spinal Solutions fusion surgery, Ms. Garrett underwent an additional surgery with Dr. Gary Dix at Anne Arundel Medical Center in 2014.

128. Ms. Garrett incurred medical expenses, including for an additional surgery that she otherwise would not have incurred had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

129. As a result of Spinal Solutions hardware being implanted in her spine, Ms. Garrett lives in fear that her substandard, recalled, and non-FDA approved hardware will fail, and suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish. Since the Spinal Solutions surgery she has been forced to wear a full body brace and walks with a cane.

Plaintiff George Graham

130. On March 23, 2010, Plaintiff George Graham, underwent a two-level lumbar fusion surgery at the L3-L4, L4-L5 levels with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

131. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of two 6.0 x 5.0 mm pedicle screws, four 6.0 x 45 mm pedicle screws, six pedicle screw caps,

and two fixation rods. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

132. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Mr. Graham's body as "Spinal Solutions pedicle screw instrumentation."

133. It is clear that during Mr. Graham's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

134. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

135. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains a product implant sticker for another product implanted during the surgery, but no such stickers or bar codes for the Spinal Solutions instrumentation.

136. Mr. Graham was billed for the substandard hardware used to perform his lumbar fusion surgery on March 23, 2010, and Mr. Graham incurred out of pocket expenses related to the procedure.

137. Moreover, UMMS/UM-BWMC committed billing fraud by billing Mr. Graham for two 4.0 mm x 12 mm Synthes Cannulated trauma screws that were not used. Interestingly, these FDA-approved screws that were not used were billed at $210.25 per screw, while the non-FDA approved Spinal Solutions screws were billed to Mr. Graham at $1,300.00 per screw.

138. Mr. Graham experienced little to no relief from the procedure.

139. Within approximately two years, Mr. Graham experienced pain caused by a seroma that formed in the area of the substandard hardware. On March 23, 2012, Mr. Graham underwent a procedure to have the seroma aspirated.

140. Mr. Graham incurred medical expenses, including for an additional procedure, which he otherwise would not have incurred had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to him prior to being implanted.

141. As a result of Spinal Solutions hardware being implanted in his spine, Mr. Graham suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish.

Plaintiff Judy Hebbard

142. On October 27, 2010, Plaintiff Judy Hebbard underwent a three-level lumbar fusion surgery at the L3-L4, L4-L5, L5-S1 levels with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

143. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of two 6.0 x 5.0 mm pedicle screws, two 6.0 x 45 mm pedicle screws, two 6.0 x 40 mm pedicle screws, six pedicle screw caps, and two fixation rods. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products

144. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Ms. Hebbard's body as "Spinal Solutions pedicle screw instrumentation."

145. It is clear that during Ms. Hebbard's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

146. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

147. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains a product implant stickers and bar codes for other products implanted during the surgery, but no such stickers or bar codes for the Spinal Solutions instrumentation.

148. Ms. Hebbard was billed for the substandard hardware used to perform her lumbar fusion surgery on October 27, 2010, and Ms. Hebbard incurred out of pocket expenses related to the procedure.

149. Moreover, UMMS/UM-BWMC committed billing fraud by billing Ms. Hebbard for two 4.0 mm x 12 mm Synthes Cannulated trauma screws that were not used. Interestingly,

these FDA-approved screws that were not used were billed at $277.69 per screw, while the non-FDA approved Spinal Solutions screws were billed to Ms. Hebbard at $1,048.95 per screw.

150. Ms. Hebbard experienced no relief from the procedure, and instead suffered from extreme pain and unrelenting numbness from the waist down. In fact, as a result of the procedure, Ms. Hebbard experienced spinal fluid leakage, was held at the hospital for ten days, and was forced to undergo an additional procedure on November 2, 2010 to drain a seroma in the area of the substandard non-FDA approved hardware and to augment the previous procedure performed by Dr. Davis.

151. Ms. Hebbard incurred medical expenses, including for an additional procedure, which she otherwise would not have incurred had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

152. As a result of Spinal Solutions hardware being implanted in her spine, and Ms. Hebbard suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish.

Plaintiff Dawn Kellar

153. On March 18, 2011, Plaintiff Dawn Kellar, underwent her first back surgery, which was an L4-L5 lumbar fusion with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

154. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of four 6.0 x 45 mm pedicle screws, four pedicle screw caps, and two fixation rods. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

155. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Mrs. Kellar's body as the "Spinal Solutions pedicle screw instrumentation."

156. It is clear that during Ms. Kellar's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

157. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

158. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains product implant stickers and bar codes for other products implanted during the surgery, but no such stickers or bar codes for the Spinal Solutions instrumentation.

159. Ms. Kellar was billed for the substandard hardware used to perform her lumbar fusion surgery on March 18, 2011, and Ms. Kellar incurred out of pocket expenses related to the procedure.

160. Ms. Kellar experienced no relief from the procedure and instead experienced constant and worsening pain thereafter.

161. On March 23, 2013, due to this continued and worsening pain, Dr. Davis performed explant surgery in which he removed all of the Spinal Solutions hardware previously implanted in Ms. Kellar's back, and then re-fused her discs without instrumentation. During the explant surgery, "definite residual motion" was identified.

162. The condition of the hardware cannot be evaluated now because Dr. Davis improperly discarded the explanted hardware without sending it to pathology or offering it to his patient. In addition, in violation of 21 C.F.R. § 803, et seq., no adverse event report was filed by Dr. Davis or UMMS/UM-BWMC.

163. Ms. Kellar incurred medical expenses, including for the explant surgery, which she would not have incurred had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

164. As a result of Spinal Solutions hardware being implanted in her spine, Ms. Kellar suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish.

Plaintiff Tammie Lane

165. Plaintiff Tammie Lane injured her back in or around 2008. Shortly after becoming Dr. Davis's patient in 2010, he prescribed instrumented spinal fusion surgery for her.

166. On June 8, 2010, Mrs. Lane underwent a three-level lumbar fusion surgery at the L2-L3, L3-L4, L4-L5 levels with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

167. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of two 6.0 x 45 mm pedicle screws, five 6.0 x 40 mm pedicle screws, one 5.0 x 45 mm pedicle screws, eight pedicle screw caps, and two fixation rods. As to each component, the manufacturer

is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

168. It is clear that during Mrs. Lane's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

169. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Mrs. Lane's body as the "Spinal Solutions pedicle screw instrumentation."

170. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

171. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains product implant stickers and bar codes for other products implanted during the surgery, but for the Spinal Solutions products there are only hand-written entries that purportedly include some kind of reference number, but that which is insufficient to trace the products used, and is likely fictitious (See ¶¶ 43-44, incorporated by reference herein.)

172. Mrs. Lane was billed for the substandard hardware used to perform her lumbar fusion surgery on June 8, 2010, and Mrs. Lane incurred out of pocket expenses related to the

procedure. Curiously, despite BWMC being billed for nine screws by Spinal Solutions, BMWS/UMMS only invoiced Mrs. Lane for seven screws, but also for eight screw caps.

173. Mrs. Lane experienced no relief from the procedure and instead experienced constant and worsening pain thereafter.

174. Mrs. Lane was thereafter diagnosed with post-fusion syndrome, and was told by Dr. Davis that she would only get relief from removal of the hardware he implanted. Mrs. Lane has not undergone removal surgery due to fear.

175. Due to the extreme pain she has been in since the instrumented fusion, in or around 2012, Mrs. Lane underwent a procedure at Johns Hopkins Hospital to have a spinal cord stimulator implanted in her body.

176. Mrs. Lane incurred medical expenses, including for implantation of the spinal cord stimulator, which she would not have incurred had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

177. As a result of Spinal Solutions hardware being implanted in her spine, Mrs. Lane suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish.

Plaintiff Dianne Marut

178. On February 22, 2011, Plaintiff Dianne Marut, underwent a two-level lumbar fusion surgery at the L4-L5 and L5-S1 levels with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

179. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of two 6.0 x 5.0 mm pedicle screws, two 6.0 x 45 mm pedicle screws, two 6.0 x 40 mm pedicle screws, six pedicle screw caps, one 7.0 x 40 mm pedicle screw, and two fixation rods. As to each

component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

180. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Ms. Marut's body as "Spinal Solutions pedicle screw instrumentation."

181. It is clear that during Ms. Marut's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

182. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

183. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains a product implant sticker for another product implanted during the surgery, but no such stickers or bar codes for the Spinal Solutions instrumentation.

184. Ms. Marut was billed for the substandard hardware used to perform her lumbar fusion surgery on February 22, 2011, and Ms. Marut incurred out of pocket expenses related to the procedure.

185. Though Spinal Solutions hardware should never have been implanted in Ms. Marut, and she should not have been billed for the substandard hardware, upon information and belief she was actually billed more for the Spinal Solutions pedicle screws than most other patients who received them. To this end, Ms. Marut was billed $2,815 for each substandard screw. By comparison, Plaintiff Tammie Lane was only billed $1048.95 for the identical pedicle screws.

186. Moreover, UMMS/UM-BWMC committed billing fraud by billing Ms. Marut for two 4.0 mm x 12 mm Synthes Cannulated trauma screws that were not used. Interestingly, these FDA-approved screws that were not used were billed at $425.85 per screw, while the non-FDA approved Spinal Solutions screws were billed to Ms. Marut at a whopping $2,815.00 per screw. Ms. Marut was even overbilled for the Synthes screws that she did not receive in that most patients who were billed for Synthes screws were billed $210.25 per screw while she was more than double for them.

187. Ms. Marut experienced no relief from the procedure and instead experienced extreme pain shortly thereafter.

188. Within one month of the surgery in which Dr. Davis implanted non-FDA approved substandard Spinal Solutions hardware in Ms. Marut, she was diagnosed with MRSA. At this point, Dr. Davis began referring to Ms. Marut as his "Little Science Project."

189. As a result of being implanted with non-FDA approved hardware, which caused Ms. Marut to contract MRSA, she was forced to undergo surgery on May 7, 2012 to have her Spinal Solutions hardware removed with Dr. Davis at UM-BWMC.

190. During the explant surgery on May 7, 2012, Dr. Davis noted that the "screws were grossly loose and purulent material was found tracking in and around the screws and into the pedicle screw holes."

191. The condition of the hardware cannot be evaluated now because Dr. Davis improperly discarded the explanted hardware without sending it to pathology or offering it to his patient. In addition, in violation of 21 C.F.R. § 803, et seq., no adverse event report was filed by Dr. Davis or UMMS/UM-BWMC.

192. Ms. Marut contracted MRSA and incurred medical expenses, including for multiple additional surgeries, antibiotics, and pain medication, which she otherwise would not have incurred, had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

193. As a result of Spinal Solutions hardware being implanted in her spine, Ms. Marut suffered and continues to suffer physical injury, infection, lymphedema, dependence on prescription antibiotics and pain medication for the rest of her life, and extreme mental anguish. She is limited in her ability to move around and is limited to walking with the assistance of a walker.

Plaintiff Deborah McCully

194. On April 20, 2011, Mrs. McCully underwent a three level lumbar fusion surgery at the L3-L4, L4-L5, and L5-S1 levels with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

195. In performing the surgery, Dr. Davis implanted four 6.0 x 50 mm pedicle screws, two 6.0 x 45 mm pedicle screws, two 6.0 x 40 mm pedicle screws, eight screw caps, and two fixation rods. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

196. It is clear that during Ms. McCully's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was

treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

197. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

198. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains a product implant sticker for another product implanted during the surgery, but no such stickers or bar codes for the Spinal Solutions instrumentation.

199. Mrs. McCully was billed for the substandard hardware used to perform her lumbar fusion surgery on April 20, 2011, and Mrs. McCully incurred out of pocket expenses related to the procedure

200. Moreover, UMMS/UM-BWMC committed billing fraud by billing Mrs. McCully for four 4.0 mm x 12 mm Synthes Cannulated trauma screws that were not used and by billing her for sixteen screw caps instead of eight. Interestingly, the FDA-approved screws that were not used were billed at $275.79 per screw, while the non-FDA approved Spinal Solutions screws were billed to Mrs. McCully at $1,818.00 per screw. She was also billed for eight screw caps at $358.25 for each and another eight at $1,044.50 for each, but only eight were used in performing her procedure.

201. Mrs. McCully experienced no relief from the procedure, and instead has suffered from extreme pain ever since.

202. Mrs. McCully incurred medical expenses, which she would not have incurred, had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

203. As a result of Spinal Solutions hardware being implanted in his spine, Mrs. McCully suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish.

Plaintiff Cathy Paquet

204. On July 27, 2010, Mrs. Paquet underwent a lumbar fusion procedure involving the implantation of a Spinal Solutions APLIF implant performed by Dr. Davis at UM-BWMC.

205. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of an 18 x 45 x 10 x 10 APLIF cage. The manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

206. It is clear that during Mrs. Paquet's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

207. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44,

incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

208. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains a product implant sticker for another product implanted during the surgery, but no such stickers or bar codes for the Spinal Solutions instrumentation.

209. Mrs. Paquet was billed for the substandard hardware used to perform her lumbar fusion surgery on July 27, 2010, and Mrs. Paquet incurred out of pocket expenses related to the procedure.

210. The APLIF device implanted in Mrs. Paquet was the subject of a recall in 2013 due to "inadequate testing and documentation to demonstrate that it meets performance or safety standards." The recall further stated that "[t]hese inadequacies might result in product performance failures that could cause patient harm due to implant breakage, movement, or inadequate sterilization."

211. Despite this recall notice being issued and publicly available on the FDA's website, neither Dr. Davis, UM-BWMC, nor UMMS informed Mrs. Paquet of the recall. Instead, UM-BWMC sent a letter to its patients, including Mrs. Paquet, on July 13, 2015, falsely reassuring them that that no "... *non-FDA approved hardware was ever delivered to or used in spinal surgeries at UM BWMC.*" (Emphasis in original).

212. Mrs. Paquet experienced no relief from the procedure and instead experienced constant and worsening pain thereafter.

213. Mrs. Paquet incurred medical expenses, which she would not have incurred, had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

214. As a result of Spinal Solutions hardware being implanted in her spine, Mrs. Paquet lives in fear that her substandard, recalled, and non-FDA approved hardware will fail, and suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish.

Plaintiff Natasha Queen

215. On October 13, 2010, Plaintiff Natasha Queen, underwent a lumbar fusion surgery at the L2-L3 level with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

216. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of two 6.0 x 45 mm pedicle screws, two screw caps, one APLIF implant, and one fixation rod. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

217. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Ms. Queen's body as "Spinal Solutions lateral pedicle screw fixation."

218. It is clear that during Ms. Queen's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

219. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

220. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains a product implant sticker for another product implanted during the surgery, but no such stickers or bar codes for the Spinal Solutions instrumentation.

221. Ms. Queen was billed for the substandard hardware used to perform her lumbar fusion surgery on October 13, 2010, and Ms. Queen incurred out of pocket expenses related to the procedure.

222. The APLIF device implanted in Ms. Queen was the subject of a recall in 2013 due to "inadequate testing and documentation to demonstrate that it meets performance or safety standards." The recall further stated that "[t]hese inadequacies might result in product performance failures that could cause patient harm due to implant breakage, movement, or inadequate sterilization."

223. Despite this recall notice being issued and publicly available on the FDA's website, neither Dr. Davis, UM-BWMC, nor UMMS informed Ms. Queen of the recall. Instead, UM-BWMC sent a letter to its patients, including Ms. Queen, on July 13, 2015, falsely reassuring them that that no "... *non-FDA approved hardware was ever delivered to or used in spinal surgeries at UM BWMC.*" (Emphasis in original)

224. Ms. Queen experienced no relief from the procedure and instead experienced constant and worsening pain thereafter.

225. Due to the failed procedure, Ms. Queen underwent an additional surgery with Dr. Davis at UM-BWMC on October 16, 2012.

226. Ms. Queen incurred medical expenses, which she would not have incurred, had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

227. As a result of Spinal Solutions hardware being implanted in her spine, Ms. Queen lives in fear that her substandard, recalled, and non-FDA approved hardware will fail, and suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish.

Plaintiff Teresa Stancliff

228. On June 22, 2010, Plaintiff Teresa Stancliff, underwent a two-level lumbar fusion surgery at the L3-L4, L4-L5 levels with implantation of Spinal Solutions instrumentation, performed by Dr. Davis at UM-BWMC.

229. In the "Intraoperative Record," the UM-BWMC operating room staff logged the use of six 6.0 x 45 mm pedicle screws, six pedicle screw caps, and three fixation rods. As to each component, the manufacturer is identified as Spinal Solutions, despite the fact that Spinal Solutions did not manufacture any products.

230. Similarly, in Dr. Davis's Operative Report, he identified the devices implanted into Mrs. Stancliff's body as "Spinal Solutions instrumentation."

231. It is clear that during Mrs. Stancliff's procedure (and all of the other lumbar fusion procedures performed by Dr. Davis during the relevant timeframe), that Spinal Solutions was

treated by all UM-BWMC employees/agents as the manufacturer of the spinal instrumentation, despite the fact that Spinal Solutions held no FDA approval or clearance for the manufacture and sale of said devices.

232. Importantly, in violation of COMAR § 10.13.02.06, 42 C.F.R. § 482.24, and 21 C.F.R. § 821.30, among other federal and state statutory and regulatory violations, no legitimate tracking information is provided in the record for any of these implanted devices. (See ¶¶ 43-44, incorporated by reference herein.) The record is also devoid of any FDA registration information or implant "stickers" that typically accompany the use of implantable medical devices.

233. Reputable manufacturers of implantable devices typically ship those devices with "implant stickers" containing the required manufacturer information, batch/lot numbers, bar codes, and/or unique device identifiers. In fact, there is an Implant Log that contains product implant stickers and bar codes for other products implanted during the surgery, but for the Spinal Solutions products there are only hand-written entries that purportedly include some kind of reference number, but that which is insufficient to trace the products used, and is likely fictitious (See ¶¶ 43-44, incorporated by reference herein.)

234. Mrs. Stancliff was billed for the substandard hardware used to perform her lumbar fusion surgery on June 22, 2010, and Mrs. Stancliff incurred out of pocket expenses related to the procedure.

235. Mrs. Stancliff experienced no relief from the procedure and instead experienced additional pain.

236. As a result of Mrs. Stancliff's pain following the Spinal Solutions surgery, she underwent explant surgery by Dr. John Carbone on September 17, 2012 at MedStar Harbor

Hospital, in which all of the non-FDA approved substandard Spinal Solutions hardware was removed and replaced with FDA-approved hardware.

237. Mrs. Stancliff incurred medical expenses, including for the explant surgery, which she would not have incurred had the substandard and non-FDA approved Spinal Solutions hardware been disclosed to her prior to being implanted.

238. As a result of Spinal Solutions hardware being implanted in her spine, Mrs. Stancliff suffered and continues to suffer physical injury, dependence on prescription pain medication, and extreme mental anguish.

239. Neither Dr. Davis nor UMMS/UM-BWMC disclosed the fact that Dr. Davis would be using non-FDA approved, "misbranded", "adulterated", and/or substandard Spinal Solutions hardware in any of the Plaintiffs' fusion procedures. Furthermore, neither Dr. Davis nor UMMS/UM-BWMC disclosed their financial incentives to use Spinal Solutions' non-FDA approved instrumentation to any of the Plaintiffs prior to operating on them.

COUNT ONE
LACK OF INFORMED CONSENT
(ALL PLAINTIFFS V. DR. DAVIS, UM-BWMC, AND UMMS)

240. Plaintiffs re-allege and incorporate by reference all previous paragraphs in this Complaint as though fully set forth herein.

241. At all times herein relevant, Dr. Davis was employed by, or was otherwise an actual or apparent agent of, UM-BWMC and UMMS.

242. Dr. Davis, as an employee and/or agent of UM-BWMC and UMMS, performed the instrumented spinal fusion surgeries on Plaintiffs, identified in paragraphs 68-239 herein, using non-FDA-approved, misbranded, adulterated, non-conforming, substandard Spinal Solutions devices.

243. Before performing the aforementioned surgeries, Dr. Davis and UM-BWMC and UMMS knew or should have known the following:

a. Spinal Solutions neither applied for nor received FDA approval to manufacture, market, and/or distribute Spinal Solutions-branded spinal fixation devices;

b. The Spinal Solutions fixation devices used in Plaintiffs' surgeries were not manufactured and/or handled in compliance with either good industry practice or the FDA regulations governing implantable medical devices;

c. The Spinal Solutions instrumentation used in Plaintiffs' surgeries were not FDA approved, and were misbranded and adulterated;

d. Neither Dr. Davis nor any physician with UM-BWMC/UMMS had ever used Spinal Solutions fixation devices prior 2005;

e. Spinal Solutions had no procedures in place to track inventory, process adverse event reports, and/or ensure quality control of the fixation devices used in Plaintiffs' surgeries;

f. Instrumented spinal fusion surgery is a very complex procedure and the use of non-FDA-approved, non-conforming, substandard, and/or counterfeit pedicle screws and/or other spinal fixation devices substantially increased the risk of negative surgical outcomes, including additional surgeries, serious and permanent physical injury, paralysis, nerve damage, and/or death resulting from broken hardware, severe surgical site infection and/or other life-threatening complications;

g. As a result of the intrusive nature of instrumented spinal fusion surgery, the non-FDA-approved and/or counterfeit spinal fixation hardware cannot be removed without reversing the fusion and significant risk of death or serious injury to the patient; and

h. That alternative spinal fixation devices that were approved by the FDA, would have minimized the risk of negative surgical outcomes, and were manufactured by companies with established track records of safety and compliance were readily available at the time Plaintiffs' surgeries were performed.

244. Dr. Davis, UMMS, and UM_BWMC owed Plaintiffs a duty to disclose all material risks or dangers associated with the instrumented spinal fusion procedures so as to enable Plaintiffs to make an intelligent and informed choice about whether or not to undergo each procedure.

245. Dr. Davis, UMMS, and UM-BWMC failed to disclose any and all of the risks stated in paragraph 243 to Plaintiffs.

246. Dr. Davis further failed to disclose to Plaintiffs:

a. That he maintained a lucrative financial agreement with Spinal Solutions;

b. That Spinal Solutions instrumentation was not approved or cleared by the FDA;

c. That Spinal Solutions instrumentation was misbranded, adulterated and/or potentially counterfeit;

d. That Spinal Solutions instrumentation was untraceable because it lacked serial, batch, and lot numbers, and/or proper unique identification numbers.

e. That no other orthopedic surgeon in UM-BWMC, the UMMS system, or in the state of Maryland, was using Spinal Solutions fixation devices to perform instrumented spinal fusion surgery;

f. That other patients on whom he had performed instrumented spinal fusion surgery using Spinal Solutions fixation devices had suffered negative surgical outcomes including serious physical debilitation and severe infection, likely caused or contributed to by the substandard Spinal Solutions devices;

g. That none of the failed fusion surgeries and/or injuries related to the use of Spinal Solutions hardware had been reported to the manufacturer of the hardware or the FDA, as required by law, and no investigation into the cause of the failures had taken place; and

h. That the failed Spinal Solutions devices had not been preserved for third party testing or subject to third party testing to determine the cause of failure.

247. Any reasonable person in Plaintiff's position would have regarded the information in the previous paragraph as not only material, but critical, to the decision to provide consent to instrumented spinal fusion surgeries using Spinal Solutions devices.

248. Dr. Davis's failure to inform Plaintiffs of the material risks and dangers in the preceding paragraphs prevented Plaintiffs from making an informed decision to consent to the procedures described in paragraphs 68-239 herein. Dr. Davis therefore, as to each procedure using

Spinal Solutions fixation devices, breached his duty to secure the fully informed consent of Plaintiffs.

249. Had Dr. Davis fully disclosed the material risks and dangers inherent in instrumented spinal fusion surgery using misbranded, adulterated and/or substandard Spinal Solutions fixation devices, Plaintiffs would have refused consent to the procedure, just as any similarly situated and reasonable patient would have done.

250. As a result of the procedures for which there was not fully informed consent given by Plaintiffs, the Plaintiffs suffered severe and permanent injuries.

251. UM-BWMC and UMMS are liable for the actions of their agents and/or employees, including Dr. Davis, pursuant to the doctrines of *respondeat superior* and vicarious liability.

252. As a foreseeable, direct, and proximate result of the aforementioned lack of informed consent, Plaintiffs sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand compensatory damages against Defendants in excess of seventy-five thousand dollars ($75,000), plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT TWO
LACK OF INFORMED CONSENT (APPARENT AGENCY)
(ALL PLAINTIFFS V. UM-BWMC, UMMS)

253. Plaintiffs re-allege and incorporate by reference all previous paragraphs in this Complaint as though fully set forth herein.

254. At all times herein relevant, Dr. Davis was acting as the apparent agent of Defendants UM-BWMC and UMMS with regard to the care and treatment of Plaintiffs. At those times, Plaintiffs were under the reasonable belief that Dr. Davis was acting under the control, supervision and/or authority of UM-BWMC and UMMS and that each held itself out to the public, and to the Plaintiffs in particular, as a full service facility capable of providing competent medical care to patients admitted to its facility. Additionally, Defendants UM-BWMC and UMMS failed to take any affirmative measures to advise Plaintiffs that Dr. Davis was not acting as an employee, agent and/or representative in connection with the care and treatment of Plaintiffs. Defendants UM-BWMC and UMMS are vicariously liable for the acts and omissions of their apparent agents, servants and employees.

WHEREFORE, Plaintiffs demand compensatory damages against Defendants in excess of seventy-five thousand dollars ($75,000), plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT THREE
FRAUD NON-DISCLOSURE
(ALL PLAINTIFFS V. DR. DAVIS, UM-BWMC, AND UMMS)

255. Plaintiffs re-allege and incorporate by reference all previous paragraphs in this Complaint as though fully set forth herein.

256. Dr. Davis, UM-BWMC, and UMMS each owed to Plaintiffs a fiduciary duty to fully and accurately disclose all material risks and dangers inherent in Plaintiffs' surgeries, including the risks and dangers associated with the use of non-FDA approved, misbranded, adulterated, non-conforming, substandard implantable spinal fixation devices manufactured and/or

distributed by Spinal Solutions, as well as Dr. Davis's relationship with Spinal Solutions from which he received direct pecuniary benefit in exchange for his use of Spinal Solutions devices.

257. Dr. Davis, UM-BWMC, and UMMS breached their fiduciary duties owed to Plaintiffs by:

a. Failing to disclose that the Spinal Solutions implantable spinal fixation devices used in their instrumented spinal fusion procedures lacked FDA approval and were misbranded and/or adulterated and not manufactured, handled, and/or distributed in accordance with good industry practice;

b. Failing to disclose that the use of non-FDA approved, misbranded, adulterated, non-conforming, substandard Spinal Solutions implantable spinal fixation devices substantially increased the risk of severe surgical complications, including infection and failed fusion, potentially resulting in permanent impairment, paralysis, death, and/or the need for additional surgeries, among others;

c. Failing to disclose that the negative surgical outcomes experienced by Plaintiffs, including permanent injury and the need for multiple additional surgeries may have been caused or contributed to by the use of non-approved, misbranded, adulterated, substandard, and/or counterfeit Spinal Solutions devices;

d. Failing to disclose that other patients on whom Dr. Davis had used Spinal Solutions devices had experienced a disproportionate number of negative surgical outcomes similar to those experienced by Plaintiffs;

e. Failing to disclose that Dr. Davis received a direct pecuniary benefit from his selection of Spinal Solutions devices in Plaintiffs' instrumented spinal fusion surgeries in violation of federal and state Anti-Kickback statutes; and

f. Failing to disclose other material information and risks associated with using non-FDA-approved, misbranded, adulterated, non-conforming, substandard implantable spinal fixation devices in Plaintiffs' instrumented spinal fusion surgeries, as more fully specified in Paragraphs 243 and 246 of this Complaint.

258. Dr. Davis, UM-BWMC, and UMMS knew that their omissions were material, and that the representations expressed by those omissions about Plaintiffs' instrumented spinal fusion surgeries were false, incomplete, misleading, deceptive, and/or deceitful when they were made. Alternatively, Dr. Davis, UM-BWMC, and UMMS made the representations by omission with

such reckless disregard for the truth that knowledge of their falsity can be imputed to Dr. Davis, UM-BWMC, and UMMS.

259. Dr. Davis, UM-BWMC, and UMMS made the misrepresentations and/or omissions for the purpose of deceiving and defrauding Plaintiffs and with the intention of having Plaintiffs act and rely on them because Dr. Davis, UM-BWMC, and UMMS derived a direct and substantial financial benefit from the use of Spinal Solutions hardware in their surgeries.

260. Plaintiffs relied with justification on the misrepresentations and omissions by Dr. Davis, UM-BWMC, and UMMS, which caused Plaintiffs to undergo surgeries in which non-FDA approved substandard and/or counterfeit spinal instrumentation was implanted in their bodies, without knowledge of all material risks.

261. The actions of Dr. Davis, UM-BWMC, and UMMS, and Plaintiffs' justifiable reliance thereon, caused and/or was a substantial contributing factor in causing them to suffer severe and permanent injuries and to incur substantial damages.

262. UM-BWMC and UMMS are liable for the actions of their agents and/or employees, including Dr. Davis, pursuant to the doctrines of *respondeat superior* and vicarious liability.

263. As a foreseeable, direct, and proximate result of the aforementioned fraudulent non-disclosure by Dr. Davis, UM-BWMC, and UMMS, Plaintiffs sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand compensatory damages against Defendants in excess of seventy-five thousand dollars ($75,000), plus litigation costs and expenses reasonably incurred;

punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT FOUR
FRAUD - CONCEALMENT
(ALL PLAINTIFFS V. ALL DEFENDANTS)

264. Plaintiffs re-allege and incorporate by reference all previous paragraphs in this Complaint as though fully set forth herein.

265. Dr. Davis, UM-BWMC, and UMMS each owed to Plaintiffs a fiduciary duty to fully and accurately disclose all material information and risks regarding their surgeries in which non-FDA approved, misbranded, adulterated, non-conforming, substandard implantable spinal fixation devices Spinal Solutions devices were implanted into Plaintiffs' bodies.

266. As Plaintiffs' health care providers, Dr. Davis, UM-BWMC, and UMMS each owed to Plaintiffs a fiduciary duty to disclose all material information related to their health and well-being and any treatment or procedures related thereto, including providing Plaintiffs with sufficient information to determine, with certainty, the exact provenance or origin of the spinal fixation devices implanted in his body.

267. Dr. Davis, UM-BWMC, and UMMS breached their duties owed to Plaintiffs by fraudulently concealing:

a. That Dr. Davis, who, prior to each surgery, prescribed the use of Spinal Solutions fixation devices, maintained a lucrative financial agreement with Spinal Solutions whereby, among other things, he derived a direct pecuniary benefit in exchange for his use of Spinal Solutions devices in violation of federal and state Anti-Kickback statutes, including through his POD(s);

b. That the Spinal Solutions fixation devices used in Plaintiffs' surgeries were not FDA approved, were misbranded and adulterated, were not manufactured, handled, and/or distributed in accordance with good industry practice, and/or were counterfeit copies of devices manufactured by third parties;

c. That Dr. Davis was prescribing the use of Spinal Solutions fixation devices with the knowledge that his patients, including Plaintiffs, had suffered serious physical injuries likely caused or contributed to by failures in the Spinal Solutions fixation devices used and that the causes of those failures were neither reported nor investigated;

d. That Plaintiffs had a right to take possession of the failed Spinal Solutions devices removed from their bodies for possible third party examination;

e. The occurrence, and rate thereof, of serious complications following spinal fusion surgeries in which Spinal Solutions devices were implanted in patients of the Dr. Davis, UM-BWMC, and UMMS between 2007 and 2012; and

f. That Plaintiffs' injuries may have been caused, or contributed to, by the use of substandard, non-FDA approved, misbranded, adulterated, non-conforming hardware, even after Spinal Solutions was shut down and under investigation for the counterfeit production of implantable medical devices.

268. Dr. Davis, UM-BWMC, and UMMS consciously and deliberately concealed the information described in the preceding paragraphs to prevent the public, including Plaintiffs, from discovering the illegal use of non-FDA approved and/or counterfeit Spinal Solutions hardware and to prevent Plaintiffs, including their representatives and health insurance providers, as well as regulatory authorities, from further investigating the details of their spinal fusion surgeries.

269. Dr. Davis, UM-BWMC and UMMS concealed these facts for the purpose of deceiving and defrauding Plaintiffs and with the intention of having them act and rely on the fraudulent concealments by failing to protect their legal rights while continuing to seek treatment with Dr. Davis, thereby enabling the continued profiting from Plaintiffs' pain and suffering by the Defendants.

270. Plaintiffs relied with justification on the misrepresentations and/or concealments by Dr. Davis, UM-BWMC, and UMMS, which resulted in Plaintiffs unwittingly providing consent for various instrumented spinal fusion surgeries using non-FDA approved, misbranded,

adulterated, non-conforming, substandard Spinal Solutions fixation devices, failing to learn the true cause of their injuries, and delaying seeking legal counsel.

271. The actions of Dr. Davis, UM-BWMC, and UMMS, and Plaintiffs' justifiable reliance thereon, caused and/or was a substantial contributing factor in causing Plaintiffs to suffer permanent and debilitating injuries, including severe emotional distress, as well as their delay in seeking legal recourse.

272. UM-BWMC and UMMS are liable for the actions of their agents and/or employees, including Dr. Davis, pursuant to the doctrines of *respondeat superior* and vicarious liability.

273. As a foreseeable, direct, and proximate result of the aforementioned fraudulent concealments by Dr. Davis, UM-BWMC, and UMMS, Plaintiffs sustained the following damages:

a. Economic losses including medical care, past and future; and lost earnings, past and future; and

b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, and loss of enjoyment and impairment of quality of life, past and future.

WHEREFORE, Plaintiffs demand compensatory damages against Defendants in excess of seventy-five thousand dollars ($75,000), plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT FIVE
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS
(ALL PLAINTIFFS V. ALL DEFENDANTS)

274. Plaintiffs re-allege and incorporate by reference all previous paragraphs in this Complaint as though fully set forth herein.

275. At all times herein relevant, Dr. Davis, UM-BWMC, and UMMS each owed to Plaintiffs a duty to make all decisions regarding their medical care solely on the basis of the individual patient's best medical interests and to comply with all applicable standards of care.

276. Dr. Davis, UM-BWMC, and UMMS intentionally and recklessly breached this duty by consciously and deliberately:

a. Selecting non-FDA approved, misbranded, adulterated, substandard, and/or counterfeit Spinal Solutions fixation devices for use in Plaintiffs' instrumented spinal fusion surgeries in order to gain a direct financial benefit;

b. Concealing the use of non-FDA approved, misbranded, adulterated, substandard, and/or counterfeit Spinal Solutions fixation devices in Plaintiffs' instrumented spinal fusion surgeries;

c. Concealing that the Spinal Solutions devices that failed and had to be removed from Plaintiffs' bodies lacked FDA approval and may have been counterfeit;

d. Re-implanting additional non-FDA approved, misbranded, adulterated, substandard, and/or counterfeit Spinal Solutions fixation devices during the Plaintiffs' revision surgeries which were necessitated by the failure of the same devices;

e. Failing to disclose to Plaintiffs the observed serious physical injuries in other patients likely suffered as a result of failures of Spinal Solutions fixation devices;

f. Failing to report the Spinal Solutions fixation device failures to the FDA after serious physical injuries were suffered by patients in order to prevent the regulatory agencies and the public, including the Plaintiffs, from discovering the inferior nature of the Spinal Solutions devices; and

g. Providing deceptive and misleading information in the July 2015 letter to their patients in an attempt to dissuade Plaintiffs from further investigating the use of non-FDA approved, misbranded, adulterated, non-conforming, substandard and/or counterfeit Spinal Solutions fixation devices in their instrumented spinal fusion surgeries.

277. The conduct of Dr. Davis, UM-BWMC, and UMMS outlined in the preceding paragraph was, at all times, extreme and outrageous.

278. As a foreseeable, direct, and proximate result of the aforementioned intentional, extreme and outrageous conduct by Dr. Davis, UM-BWMC, and UMMS, Plaintiffs sustained severe and sustained emotional distress.

WHEREFORE, Plaintiffs demand compensatory damages against Defendants in excess of seventy-five thousand dollars ($75,000), plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT SIX
MD CONSUMER PROTECTION
MD. CODE ANN., COM. LAW §13-301 *ET. SEQ.*
(ALL PLAINTIFFS V. ALL DEFENDANTS)

279. Plaintiffs re-allege and incorporate by reference all previous paragraphs in this Complaint as though fully set forth herein.

280. Dr. Davis, UM-BWMC, and UMMS provided medical care to Plaintiffs and subsequently generated invoices for that care, including the cost of the Spinal Solutions devices used in Plaintiffs' instrumented spinal fusion surgeries.

281. The Maryland Consumer Protection Act excludes conduct related to medical care rendered to a patient, with the exception of the billing practices of health care providers, such as Dr. Davis, UM-BWMC, and UMMS, which are indeed contemplated by the Act. *See Scull v. Groover, Christie & Merritt, P.C.*, 435 Md. 112, 125, 76 A.3d 1186, 1193 (2013).

282. Dr. Davis, UM-BWMC, and UMMS had actual and/or constructive knowledge that the Spinal Solutions fixation devices used in Plaintiffs' spinal fusion surgeries were not FDA approved and, further, Dr. Davis, UM-BWMC, and UMMS had actual and/or constructive knowledge that the Spinal Solutions hardware was not manufactured, handled, sold and/or

distributed in accordance with good industry practice, and therefore was of little or no economic value.

283. Dr. Davis, UM-BWMC, and UMMS engaged in unfair and deceptive trade practices in violation of the Maryland Consumer Protection Act, Md. Code Ann. Com. Law Art. §13-303, by billing Plaintiffs, their private insurance companies, as well as state and federal assistance programs, thousands of dollars after each surgery for non-FDA approved, misbranded, adulterated, non-conforming, substandard and/or counterfeit Spinal Solutions devices they knew to have little or no economic value.

284. Further, Defendants UM-BWMC and UMMS arbitrarily billed Plaintiffs wildly varying amounts for the identical Spinal Solutions devices even though the cost to UMMS/UM-BWMC was the same in each case. By way of example only, on April 20, 2010, Plaintiff Mary Boddie was billed for $1300 for each 6.0 x 45 mm Spinal Solutions screw, while Plaintiff Le Anne Baker was only billed $1048.95 for the same screws on November 16, 2010, and Plaintiff Dawn Kellar was billed $2,815.15 for each of the same screws on March 18, 2011.

285. Defendants also fraudulently billed Plaintiffs by billing them for 4.0 mm x 12 mm Synthes Cannulated trauma screws that were not actually used in any of their surgeries.

286. Further, Dr. Davis, UM-BWMC, and UMMS provided little or no detail as to the origin or provenance of the Spinal Solutions devices in the invoices, and the invoices generated by UMMS/UM-BWMC after numerous surgeries are inconsistent with other records indicating what was used.

287. These billing practices of Dr. Davis, UM-BWMC, and UMMS fraudulently induced the payment of hundreds of thousands, if not millions, of dollars by their patients, including Plaintiffs, their private health insurance companies, and/or state and federal assistance

programs and left Plaintiffs without any definitive way of identifying the actual spinal fixation devices implanted into their bodies.

288. As a direct and proximate result of the unlawful and deceptive trade practices described in the preceding paragraphs, Plaintiffs are entitled to damages and such other orders and judgments which may be necessary to disgorge Dr. Davis, UM-BWMC, and UMMS of ill-gotten gains and to restore Plaintiffs.

WHEREFORE, Plaintiffs demand compensatory damages against Defendants in excess of seventy-five thousand dollars ($75,000), plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT SEVEN
CIVIL CONSPIRACY
(ALL PLAINTIFFS V. ALL DEFENDANTS)

289. Plaintiffs re-allege and incorporate by reference all previous paragraphs in this Complaint as though fully set forth herein.

290. The use of non-FDA approved, misbranded and/or adulterated, non-conforming, substandard and/or counterfeit Spinal Solutions devices was in violation of state and federal law.

291. These unlawful acts required conscious and deliberate agreement among the Defendants in furtherance of the conspiracy.

292. At all times relevant, each of the Defendants was a sophisticated participant in the health care industry and expressly aware that the purchase and use of non-FDA approved, misbranded, adulterated, non-conforming, substandard and/or counterfeit Spinal Solutions devices was unlawful and posed serious risk of substantial harm to their patients.

293. With this knowledge, the Defendants, among other things, entered into agreements with Spinal Solutions and related entities, purchased the Spinal Solutions devices, subverted hospital procedures for vendor procurement, failed to disclose material risks to patients, engaged in false billing practices, and concealed their conduct after the fact via the July 2015 letter.

294. Each of these overt acts, among others, was in furtherance of the aforementioned unlawful conduct and caused severe and permanent damage to the Plaintiffs.

WHEREFORE, Plaintiffs demand compensatory damages against Defendants in excess of seventy-five thousand dollars ($75,000), plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law.

COUNT EIGHT
LOSS OF CONSORTIUM
(PLAINTIFFS DANNY BAKER, SORAYA BRASHEARS, OLETTA GRAHAM, WAYNE MCCULLY, RICHARD PAQUET, KEITH STANCLIFF V. ALL DEFENDANTS)

295. Plaintiffs re-allege and incorporate by reference all previous paragraphs in this Complaint as though fully set forth herein.

296. As a direct and proximate result of the fraudulent and otherwise tortious actions of Defendants as set forth above, Plaintiffs Danny Baker, Soraya Brashears, Oletta Graham, Wayne McCully, Richard Paquet, and Keith Stancliff have been caused to suffer severe mental anguish and emotional pain and have lost and been deprived of the advice, aid, assistance, attention, care, comfort, companionship, counsel, services, society, and support of their spouses.

297. All of the Plaintiffs' injuries and damages were caused by the wrongful acts and omissions of the Defendants, directly and by and through their actual and apparent agents, servants, and/or employees, without any negligence on their part contributing thereto.

WHEREFORE, Plaintiffs demand compensatory damages against Defendants in excess of seventy-five thousand dollars ($75,000), plus litigation costs and expenses reasonably incurred; punitive damages allowed by law to be determined by a jury at trial of this action; pre-judgment interest; post-judgment interest; and attorney's fees recoverable by law

TIMELINESS AND TOLLING OF STATUTE OF LIMITATIONS

298. Plaintiffs filed this lawsuit within the applicable limitations period of first suspecting that Spinal Solutions non-FDA approved, misbranded, adulterated, substandard and/or counterfeit spinal fusion instrumentation was used or permitted to be used by Defendants in performing their surgeries. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the Spinal Solutions instrumentation-induced injuries at an earlier time, because, at the time Plaintiffs sustained their injuries, the cause was unknown to Plaintiffs.

299. Plaintiffs did not suspect, nor did they have reason to suspect, the cause of their injuries, or the tortious nature of Defendants' conduct causing their injuries, until less than the applicable limitations period prior to the filing of this action.

300. Plaintiffs' claims are based on Defendants' affirmative involvement in concealing their financial relationships and incentives to use Spinal Solutions instrumentation and concealment of the lack of approval or clearance of these fixation devices by the FDA. Moreover, the nature of the defects in the hardware was such that they were imperceptible to Plaintiffs because they were implanted in their bodies.

301. Plaintiffs neither knew nor had reason to know that Defendants were engaging in affirmative conduct whereby they concealed the lack of FDA approval, quality, and performance of the implants.

302. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Through their verbal misrepresentations and omissions to Plaintiffs with regard to the lack of approval and quality of the instrumentation used and the financial incentives to use it, and their false representations in Plaintiffs' medical records and billing records regarding the proper manufacturer, distributor, and tracking information pertaining to the instrumentation, Defendants actively concealed from Plaintiffs the nature and quality of the instrumentation used to perform their lumbar fusion surgeries risks, and the financial incentive to use the same.

303. Furthermore, on July 13, 2015, just after a Whistleblower Complaint filed in California was unsealed and revealed DR. Davis and UMMS as Defendants therein, Karen Olscamp, President and COO of UM-BWMC penned a patently deceitful "hush" letter to patients who underwent lumbar fusion surgeries in which Spinal Solutions instrumentation was used. Despite the fact that Spinal Solutions had already been publicly cited and warned by the FDA for failing to comply with good manufacturing practices, having actual knowledge that Spinal Solutions devices did not have requisite tracking information, *i.e.*, serial, lot, batch, catalog, or unique identifying numbers, that would allow for determination of the origin of the hardware, and having actual or constructive knowledge that Spinal Solutions held no 510(K) clearances or PMA approvals from the FDA, Ms. Olscamp made the following false statements to UM-BWMC/UMMS patients the following:

- "*We want to assure you that we have found no evidence to date that any of the alleged non-FDA approved hardware was ever delivered to or used in spinal surgeries at UM BWMC.*" (Emphasis in original).
    - All of the Spinal Solutions hardware was non-FDA approved because, at a minimum, Spinal Solutions did not have FDA approval for any of the products, the products were not traceable, and therefore, they were all misbranded and adulterated.

- "Thus far, we have found no evidence that the alleged non-FDA approved hardware was ever received or used in spinal surgeries at the hospital."
    - To the contrary, all of the available evidence, *i.e.*, invoices from Spinal Solutions to UM-BWMC and patient medical and billing records, shows that non-FDA approved hardware was received and used in spinal surgeries at the hospital.
- "Our records do indicate that some of the materials used in your procedure were supplied by Spinal Solutions; therefore, we wanted to let you know we have reviewed your medical record carefully, and to assure you there is no reason for concern and no evidence that you received any of the alleged non-FDA approved hardware."
    - In addition to the obvious, being that this statement is false because all Spinal Solutions hardware was all non-FDA approved, what is more egregious, is that Ms. Olscamp claims that the medical record confirms the safety and quality of the devices implanted. In actuality, the medical records confirm the opposite and are devoid of the necessary information allowing for a determination as to the origin of any of the devices. Moreover, stating that materials were "supplied" by Spinal Solutions is disingenuous because every entry in every Plaintiffs' medical records with regard to Spinal Solutions, identifies Spinal Solutions as the manufacturer of the products, not the distributor or supplier. Accordingly, no one can tell from the records who manufactured the devices implanted in Plaintiffs' bodies if it was not Spinal Solutions.

304. As a result of Defendants' actions, Plaintiffs were unaware, and could not reasonably known or have learned through reasonable diligence, that the Plaintiffs had been exposed to the defects and risks alleged herein, and that those defects and risks were the direct and proximate result of Defendants' acts and omissions. Due to the fact that the Spinal Solutions hardware was inside of Plaintiffs' bodies, or in the instances where it was removed, it was discarded by the Defendants without being given to the patient or sent to pathology, and through Defendants' affirmative misrepresentations and omissions pertaining to the nature, quality, safety, efficacy, of the Spinal Solutions hardware, and their financial incentives to use said hardware, Plaintiffs were prevented from discovering this information sooner.

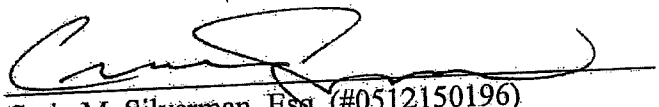
305. Therefore, the statute of limitations on Plaintiffs' claims are tolled by fraudulent concealment and equitable tolling. Accordingly, Plaintiffs' claims are timely.

306. Defendant is equitably estopped from relying on the defense of limitations until the time that Plaintiffs' right of action was, or in the exercise of reasonable diligence should have been, discovered.

307. Due to imperceptible defects in the Spinal Solutions hardware by virtue of it being implanted in Plaintiffs' bodies, and in reliance on Defendants' letter falsely assuring Plaintiffs "there is no reason for concern and no evidence that you received any of the alleged non-FDA approved hardware," Plaintiffs were unable to know of their injuries at the time of their actual accrual.

308. Accordingly, the discovery rule and equitable fraud tolling provide exceptions to the statute of limitations as to Plaintiffs' claims.

SULLIVAN, PAPAIN, BLOCK, McGRATH & CANNAVO, P.C.



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DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial on all claims in this action pursuant to Maryland Rule 2-325.

Craig M. Silverman, Esq.

RULE 1-313 CERTIFICATION OF ADMISSION TO PRACTICE LAW IN MARYLAND

I HEREBY CERTIFY that I, Craig M. Silverman, Esq., am admitted to the Maryland Bar and am currently a member in good standing.

Respectfully submitted,

SULLIVAN, PAPAIN, BLOCK,
McGRATH & CANNAVO, P.C.

Craig M. Silverman, Esq. (MD Client Protection Fund #0512150196)